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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,726	11/28/2000	Gyula Hadlaczky	119354-00002 / 402E	7776

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EXAMINER	
PAGE, BRENT T	

ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/724,726	HADLACZKY ET AL.	
	Examiner	Art Unit	
	BRENT PAGE	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-52,73-79,81,84,87-95,97-99,101,104,108,111,114,115,117,119-121 and 128* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 50-52,73-79,81,84,87-95,97-99,101,104,108,111,114,115,117,119-121 and 128.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/2008 has been entered.

The addition of claim 128 is hereby acknowledged.

Claims 50-52, 73-79, 81, 84, 87-95, 97-99, 101, 104, 108, 111, 114-115, 117, 119-121 and 128 are pending and examined on the merits herein. The DECLARATION, filed by Applicant, known as DECLARATION 8, by Michael Lindenbaum is hereby acknowledged and fully considered.

All claim objections and rejections of record not specifically addressed below are considered hereby withdrawn in response to Applicants arguments when taken together with the claim amendments.

Response to Preliminary Arguments

Applicant's arguments filed 11/14/2008 have been fully considered but they are not persuasive.

Applicants urge that centromeric sequences are not necessary to identify SATACs, reiterating previous arguments of record (pages 7-8 of response).

This is not persuasive because by Applicants own definition of SATACs, autonomous replication and a centromere are required for the structure to be considered a SATAC. The specification contains no working examples of either SATAC formation, isolation, or generation in plants. The state of the art has been established in prior office actions and the state of the art suggests that it would not have been merely routine in the art to apply the teachings regarding mammalian chromosomes to plant chromosomes. There is no guidance in the specification that indicates the recognition of the centromere and thus, the SATAC in a plant cell. A single generation of plants grown in the absence of a selection marker is not sufficient to demonstrate stable inheritance patterns for an autonomously replicating chromosome with a fully functioning centromere. In fact, according to the specification, the work in mammalian artificial chromosomes, where the state of the art is significantly advanced in relation to plant artificial chromosomes, a single generation in the absence of selection marker is not relied upon for the identification and demonstration of SATAC formation.

Applicants primarily urge that the invention being claimed is not drawn to assembling SATACs in vitro (pages 8-10 of response).

This is not persuasive because the claims are not limited to only generating SATACs *de novo* as urged by Applicant. The claims are drawn to introducing SATACs into a plant cell via any method taught in the specification, including whole, in vitro assembled SATACs. Therefore the claims will remain rejected for the reasons of record as the rejections still apply to the broadly drawn claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is

noted that the features upon which applicant relies (i.e., *de novo* centromere formation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 112-enablement

Claims 50-52, 73-79, 81, 84, 87-95, 97-99, 101, 104, 108, 111, 114-115, 117, and 119-121 remain rejected and claim 128 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims remain rejected for the reasons of record in the office actions filed 07/11/2007, 05/14/2008 as well as the reasons presented below.

Applicants arguments filed 11/14/2008 have been fully considered but they are not persuasive.

Applicants urge that the detailed identification of SATACs in the specification is simply outlining the various methods that may be used in identifying characteristics of the SATACs (see pages 11-13 of response).

This is not persuasive because it is not clear from the specification which methods may be used with plants and which may not. The listed identifications, G-banding, C-banding, immunofluorescence, electron microscopy and Southern blot all

are methods that would NOT work in plants because all rely on features that are not present in plant cells and plant chromosomes. While DECLARATION 3 has been presented to demonstrate this evidence, the specification does not give guidance for this method in plants, and the DECLARATION may not substitute as an enabling disclosure. Even with the declaration, it is noted that only a single generation in the absence of selection pressure is presented which does not definitively prove the existence of a functioning centromere.

Applicants urge that fluorescence *in situ* hybridization was known in the art at the time of filing.

This is not persuasive because Applicants are urging that the exact same steps and methods are being followed to generate plant SATACs. Different probes and different hybridization materials would have been required for plant in situ hybridization.

Applicants urge primarily, that once the demonstration of SATAC formation of mammalian cells was disclosed, that it is not necessary to disclose the same detailed analysis to show the generation of SATACs in plants because the identifying characteristics are the same across species (see pages 14-16 of the response).

This is not persuasive because the state of the art in mammalian cytology and artificial chromosome generation versus the state of the art in plant cytology and artificial chromosome generation are vastly different, even in the present day, more than a decade after filing and certainly at the time of filing. The evidence has already been cited that shows the differences known at the time of filing between the two arts. Furthermore, the tools to perform the detailed analysis for plants were not known at the

time of filing. It is submitted therefore, that it would not have been possible to know that the identifying characteristics of SATACs were the same between mammalian SATACs and plant SATACs because it wasn't possible to identify the same structural features in plants that were identified and demonstrated in the specification.

Applicant urges that the specification does not require the absence of a selective agent for the measurement of stability of the chromosome and that DECLARATION 3 provides evidence that such stability was exhibited even in the absence of a selective agent (see pages 16-18 of response).

This is not persuasive because as discussed above and in the other office actions, there was additional evidence available for the presence of a centromere and centromeric sequences in mammalian SATACs. As discussed previously, in the absence of such evidence and in the absence of similar tools, a different standard must be applied to plants to show the presence of a centromere as required by SATACs according to the definition of the instant specification. Furthermore the transmission does not even definitively show the presence of a centromere. For example, in a study of the transmission of acentric chromosomes Kanda et al (2000 J. Cell Biochem Suppl. 35:107-114) disclose that some acentric chromosomes are stably transmitted through successive cell divisions. Kanda et al propose that chromosomes may "tether" to a host chromosome and show stable transmission (see abstract and page 109 in particular). The acentric chromosomes in this case use the cells machinery to replicate and are not autonomously replicating (see page 109). Given the state of the art, the mere presence

of a chromosomal fragment does not give evidence of a SATAC as defined by the specification.

Applicants urge that cited references do not take into account the disclosure of the instant specification in regard to SATACs (see page 19-20 of response).

This is not persuasive because the state of the art has been established. The teachings of the specification are taken into account upon examination and are found to not give guidance in enough detail, particularly because this is a pioneering technology, for one of skill in the art to make and use and practice the instantly claimed invention. Applicants attention is drawn to claims that are drawn to isolating the SATAC and directly introducing the SATAC into plant cells. There is no support literally, or in DECLARATIONS to indicate that this may be done with plant SATACs, particularly at the time of filing when chromosomal manipulation in plants was in its infancy. It is precisely because of the novelty aspect of the invention that a detailed disclosure is required for enablement. One of skill in the art would have appreciated at the time of filing the vast differences between plant and mammalian cells and chromosomes and would not have expected routine experimentation to result in the successful generation of SATACs in plants. The specification does not show or disclose the successful generation of SATACs in plants. No publications of record in the decade since the time of filing have shown the successful generation of SATACs in plants. The DECLARATIONs of record show chromosomal fragments in cells with no demonstration that such fragments, are in fact, SATACs. For these reasons, in addition to the reasons

of record, it is incumbent on Applicants to provide a full disclosure of the technology to be patented.

Applicants urge that the specification is not limiting to the ways of generating SATACs and that size and number of chromosomes do not need to be known to generate SATACs and that Example 10 is not the only way to isolate SATACs (pages 21-22 of response).

These are not persuasive arguments because one of skill in the art is not given sufficient guidance to know which methods would work and which would not work in plants. Furthermore, as discussed above, wherein the tools and information available for mammalian cells are not available for plant cells, additionally information is necessary to determine success. The specification does not give guidance for determining this information or give guidance indicating the necessity of this information. See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

It is believed that all arguments regarding enablement are addressed above and in previous office actions.

Claim Rejections - 35 USC § 112-written description

Claims 1-5, 10-18, 20-22 and 24-27 remain rejected and claim 28 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description

requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims remain rejected for the reasons of record in the office actions filed 07/11/2007, 05/14/2008 as well as the reasons presented below.

Applicants arguments filed 11/14/2008 have been fully considered but they are not persuasive.

Applicants urge that the specification clearly describes the relevant identifying characteristics of SATACs (see pages 25-26 of response).

This is not persuasive because as previously discussed, many of the characteristics regarding identification (i.e. g-banding and c-banding, and centromeric regions) for mammalian SATACs can not readily be applied to plant SATACs.

Applicants urge that there is no requirement that all species within a genus be reduced to practice, nor that the specification include all examples of all species within a genus (page 26 of response).

This is not persuasive because the genus referred to by Applicant is already patented. However because this case is drawn to plant SATACs the genus of the instant case is the generation of plant SATACs. There are no embodiments described or disclosed and there are no working examples.

Applicant requests the Examiner point out where in the specification the known centromeres for mammalian SATACs are found and urge that none of these features are necessary for the generation of SATACs (pages 27-29 of response).

This is not persuasive because the specification on page 73, identifies sequences, mouse minor satellite DNA that specifically localizes to the centromeres of all mouse chromosomes. The specification also describes antibodies to known centromere associated proteins in mammalian cells for the recognition of SATACs, another tool not available for the recognition of plant SATACs.

Applicants urge that the DECLARATIONS show plant SATACs (page 30 of response).

This is not persuasive because a DECLARATION may not be relied on in place of the specification for describing essential subject matter and showing possession over the full scope of the claims.

No claims are allowed.

The claims are free of the prior art given the failure of the prior art to teach or reasonably suggest a method of introducing a satellite artificial chromosome into a plant cell with substantially more heterochromatin than euchromatin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Russell Kallis/
Primary Examiner, Art Unit 1638
December 19, 2008